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An International Association For Pharmaceutical Science And Technology

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US Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Ref.: *DRAFT Guidance for Industry ChromPAC, Manufacturing Chromatography Systems Post-approval Changes: Chemistry, Manufacturing and Controls Document* submitted to Docket #03N-0059 - Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach

Dear Sir/Madam:

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical and biopharmaceutical manufacturing and quality.

PDA is pleased to provide this original proposal for a DRAFT Industry Guidance entitled *DRAFT Guidance for Industry ChromPAC, Manufacturing Chromatography Systems Post-approval Changes: Chemistry, Manufacturing and Controls Document* to Docket number 03N-0059 as a proposed guidance for post-approval change for FDA's future consideration under the *Pharmaceutical cGMPs for the 21st Century: A Risk Basked Approach Initiative*. FDA's recent risk management initiatives have addressed incorporating best practices to simplify the regulatory requirements and reduce regulatory reporting burden through a risk-based approach contingent on the level of scientific understanding of how manufacturing process factors affect product performance. The proposed industry guidance is consistent with FDA's stated goal of identifying opportunities for reducing application submission and filing requirements. It offers a framework for FDA and industry to agree on the appropriate reporting level and test documentation requirements based on the potential for a given change to adversely affect the product. The proposed guidance addresses post-approval changes to drug substance manufacturing processes for chromatography systems.

The proposed guidance describes chemistry, manufacturing, and controls information and documentation in support of each change and provides recommendations on reporting categories based on the potential for a specified change to have an adverse effect on the drug substance/drug product. It would permit less burdensome notice of certain chromatography systems post-approval changes contingent on the applicant providing the

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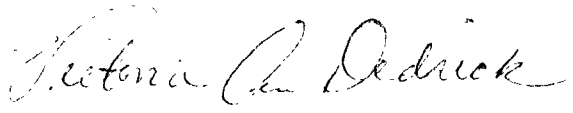
appropriate test documentation as outlined in this proposed guidance for industry.

The proposed guidance includes change tables that define: 1) levels of change; 2) examples of changes within that level; 3) recommended chemistry, manufacturing, and controls test documentation for each level of change; and 4) filing category for the chromatography system change(s). The proposed guidance accordingly sets forth application information that should be provided to assure continuing product quality and performance characteristics of products for specified post-approval changes. The proposed guidance emphasizes the need to compare the product derived from the modified process to the one derived from the currently registered process, essentially to ascertain that introduction of the change(s) did not alter the physico-chemical and biological characteristics of the product.

If you have any questions regarding our proposal, or how we may assist with further development of the Guidance, please contact me.

Yours sincerely,



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